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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/852,659	05/11/2001	Steven M. Ruben	PZ003P4	5111

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EXAMINER

SULLIVAN, DANIEL M

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 11/18/2002.

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/852,659

Applicant(s)

RUBEN ET AL.

Examiner

Daniel M Sullivan

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 September 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,13,17-19 and 24-75 is/are pending in the application.
- 4a) Of the above claim(s) 1,13 and 17-19 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 24-26,28-32,34 and 35 is/are allowed.
- 6) ☒ Claim(s) 27, 33 and 36-75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

This Office Action is a response to the Amendment and Reply under 37 C.F.R. § 1.111 filed September 4, 2002 (Paper No. 15) in response to the Office Action mailed June 4, 2002 (Paper No. 13). Claims 1, 13, 17-19 and 24-75 are pending in the Application. Claims 1, 13 and 17-19 were withdrawn from consideration in Paper No. 13. Claims 24, 28, 34, 39, 44, 49, 54, 59, 64, 69 and 74 were amended in Paper No. 15. Claims 24-75 are pending in the application.

Response to Arguments

Double Patenting

Applicant was advised in Paper No. 13 that should claims 24, 25 or 26 be found allowable, claims 30, 31 or 32, respectively, would be objected to under 37 C.F.R. § 1.75 as being a substantial duplicate thereof. In response, Applicant argues that, for several reasons set forth in Paper No. 15 (pages 3-4), the scope of claims 24, 25 and 26 is substantially different from the scope of claims 30, 31 and 32, respectively. Applicant's argument is persuasive; therefore, claims 30, 31 or 32 will not be objected to upon allowance of claims 24, 25 or 26.

Claim Rejections - 35 USC § 112, First Paragraph

Rejection of claims 28, 34, 39, 44, 49, 54, 59, 64, 69 and 74 under 35 U.S.C. § 112, first paragraph, as lacking enablement is withdrawn. The rejection was made on the grounds that the claims, being drawn to a composition comprising the protein of the instant invention in a pharmaceutically acceptable carrier, encompass compositions to be used for pharmaceutical purposes including protein therapy. The rejection is withdrawn in view of the amendment of the

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claims in Paper No. 15 such that they are no longer directed to a composition comprising a pharmaceutically acceptable carrier.

Claims 27, 33 and 36-75 stand rejected under 35 U.S.C. § 112, first paragraph, as lacking written description for reasons of record in Paper No. 13.

Claims 27, 33, 38, 43, 48, 53, 58, 63, 68 and 73 were rejected on the grounds that the disclosure does not adequately describe the genus of any and all polypeptides heterologous to SEQ ID NO:85. Applicant did not address these grounds for rejection in the reply; therefore the rejection stands.

Claims 36-55 were rejected on the grounds that the disclosure does not adequately describe the genus of any and all polypeptides that are 90% or 95% identical to SEQ ID NO:85, and claims 56-75 were rejected on the grounds that the disclosure does not adequately describe the genus of any and all polypeptides consisting of at least 30-50 contiguous amino acid residues of amino acid residues 1 to 121 or SEQ ID NO:85. Applicant's arguments regarding these rejections filed in Paper No. 15 have been fully considered but they are not persuasive.

In response to the rejection, Applicant argues that the Examiner has misrepresented the ability of the ordinary skilled artisan in asserting that one of ordinary skill would not be able to recognize polypeptides 90% or 95% identical to the polypeptides set forth as SEQ ID NO:85 or encoded by the HPMBQ91 cDNA. Applicant points out that the specification provides a specific polypeptide sequence (i.e. SEQ ID NO:85), an ATCC Deposit and specific mathematical formulae (90% and 95% identity; 30 and 50 contiguous amino acids) which may be used to identify the claimed invention, asserting that the structure of the claimed polypeptides and

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identifying characteristics have been provided for the claimed genus of sequences via provision of an explicit amino acid sequence, a biological deposit, and provision of precise, quantifiable mathematical formulae with which to predict and identify all members of the claimed genus.

Inherent in this argument is the assumption that the “identifying characteristics” of a polypeptide lie in the primary structure (i.e. amino acid sequence) of said polypeptide, as the structure and formulae provide no more than that for the claimed polypeptides with the exception the polypeptides set forth as SEQ ID NO:68 and 85.

First, it should be pointed out that the claims are directed to the polypeptides themselves, not the amino acid sequence, and therefore encompass more than the primary structure of the polypeptide. According to the Revised Interim Guidelines, identifying characteristics include, “structure or other physical and/or chemical properties,...functional characteristics coupled with a known or disclosed correlation between function and structure or... a combination of such identifying characteristics...” (Federal Register, Vol. 66, No. 4, page 1106, column 3, second full paragraph). Although the skilled artisan would be able to envision the primary structure of a polypeptide that is 90% or 95% identical to the polypeptide set forth as SEQ ID NO:85 or fragments of SEQ ID NO:85, it is presently impossible to visualize the higher order structure of a polypeptide, which is encompassed by the claims, based solely on a disclosed primary structure. Because the actual structure of most polypeptides (i.e. beyond primary amino acid sequence) is unknown, possession is usually demonstrated by correlation of function and structure as exemplified by the correlation of sequence set forth as SEQ ID NO:85 with the function of neurokinin B. No such correlation has been established in the instant disclosure for the genus of

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any and all polypeptides having 90% or 95% identity to the sequence set forth as SEQ ID NO:85 or fragments of 30 and 50 contiguous amino acids of SEQ ID NO:85.

Applicant also asserts that the rejection is based on improper legal reasoning, claiming that the Examiner has set reduction to practice as the only means to demonstrate conception. Applicant correctly points out that there are many ways to demonstrate possession; however, the Examiner's statement, quoted on page 7 of Paper No. 15, was meant to apply only to the instant case wherein "[t]he skilled artisan cannot envision the detailed chemical structure of the encompassed sequences...". The Examiner was not asserting that reduction to practice is the only way to demonstrate possession. Instead, the Examiner is merely pointing out that in the absence of all other means of satisfying the written description requirement, as in the instant case, reduction to practice is necessary.

In view of these considerations, a skilled artisan would not have viewed the teachings of the specification as sufficient to show that the applicant was in possession of the claimed invention commensurate to its scope because it does not provide adequate written description for the broad class of *any* and *all* polypeptides having 90% or 95% identity to the sequence set forth as SEQ ID NO:85 or fragments of 30 and 50 contiguous amino acids of SEQ ID NO:85. Therefore, only the described polypeptides set forth as SEQ ID NO:68 and 85 meet the written description provision of 35 U.S.C. §112, first paragraph.

Claim Rejections - 35 USC § 112, Second Paragraph

Rejection of claim 24, and claims 25-28 insofar as they depend from claim 24, under 35 U.S.C. § 112, second paragraph, as being indefinite in its recitation of "comprising amino acid

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residues 19 to 121 of SEQ ID NO:85” is withdrawn in view of the amendment of claim 24 in Paper No. 15 such that it is no longer indefinite.

Rejection of claims 25 and 26 under 35 U.S.C. § 112, second paragraph, for failing to further limit the subject matter of claim 24 from which they depend, is withdrawn in view of the clarification provided in Paper No. 15 (the paragraph bridging pages 9 and 10).

Rejection of claims 30 and 41 under 35 U.S.C. § 112, second paragraph, for being indefinite in their recitation of “secreted portion of the polypeptide encoded by the HPMBQ91 cDNA contained in ATCC Deposit No. 209070”, is withdrawn in view of the clarification provided in Paper No. 15 (page 10, first full paragraph).

Rejection of claims 27, 33, 38, 43, 48, 53, 58, 63, 68 and 73 under 35 U.S.C. § 112, second paragraph, for being indefinite in their recitation of “a polypeptide sequence heterologous to SEQ ID NO:85”, is withdrawn in view of the clarification provided in Paper No. 15 (the paragraph bridging pages 10 and 11).

Allowable Subject Matter

Claims 24-26, 28-32, 34 and 35 are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 703-305-4448. The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-9105 for regular communications and 703-746-9105 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

dms
November 6, 2002



JAMES KETTER
PRIMARY EXAMINER